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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,698	02/10/2000	ODILE LEROY	99849-A	7060

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MICHAEL S GREENFIELD
MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
CHICAGO, IL 60606

EXAMINER

FIELDS, IESHA P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/07/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,698

Applicant(s)

LEROY, ODILE

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed February 1, 2002 (Paper No. 10) has been received and entered. Claims 1-3, 5,7,9,12-18, 20, 22, and 23 were amended and new claim 24 was added. Consequently, claims 1-24 are pending in the instant application.

Response to Amendment

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. Claims 1-23 rejected under 35 U.S.C. 112, first paragraph, is **maintained**. This rejection is further applied to new claim 24.

Applicants assert that *Streptococcus pneumoniae* serotypes/serogroups and their polysaccharides are well known in the art. Applicants further assert that according to the written description guidelines "The description need only describe in detail that which is new or not conventional". Applicants further assert that the claimed invention is directed to a composition comprising a plurality of different conjugates and that the specification teaches that the invention may employ any polysaccharide derived from any *Streptococcus pneumoniae* serotypes/serogroups.

Applicant's arguments have been carefully considered but not deemed persuasive.

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As the applicant has indicated in the remarks, the claimed invention is directed to a composition comprising a plurality of different conjugates derived from any *Streptococcus pneumoniae* serotypes/serogroups. The Written Description does not provide sufficient description for a composition which comprises a "plurality" of different conjugates derived from "any" *Streptococcus pneumoniae* serotypes/serogroups".

As stated previously, the specification and claims do not indicate what distinguishing attributes are shared by any of the serotypes/serogroups of *Streptococcus pneumoniae*. The scope of the claims includes numerous structural variants and because the disclosure fails to describe the common attributes or characteristics that identify all of the members encompassed by the claimed invention, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of all of the serotypes/serogroups of *Streptococcus pneumoniae*.

2 Claims 1 and 14 rejected under 35 U.S.C. 112, second paragraph, is **withdrawn** in view of Applicants amendment to the claims.

3. Claims 1-23 rejected under 35 U.S.C. 112, second paragraph, is **maintained**.

Applicants have asserted that "the phrase a polysaccharide...derived from a *Streptococcus pneumoniae* serotype/serogroup" would be clear to one skilled in the art in view of the specification and common usage in the art. Applicants have further argued that several U.S. patents recite similar language without defining the phrase within the document.

Applicant's arguments have been carefully considered but not deemed persuasive.

As stated previously, one skilled in the art would be unable to determine the metes and bounds of a limitation which recites "derived from *Streptococcus pneumoniae*". The claims may encompass unknown modifications to the protein. Without a more clear definition one of skill in the art would be unable to replicate the claims.

Regarding the argument that other issued U.S. patents recite similar language without defining the phrase within the document, this argument is not persuasive since each application is examined based on its own merits.

Claim Rejections - 35 USC § 103

5. Claims 1- 9 and 12-15 rejected under 35 U.S.C. 103(a) as being anticipated by Marburg et al. in view of Matuhashi et al. is **maintained**. This rejection is further applied to new claim 24.

Applicants have disagreed with the conclusion by the Examiner that one skilled in the art would be motivated to employ more than one protein carrier to boost an immunological response and expect a reasonable amount of success in doing so. The applicant has cited art which teaches uncertainty as to the affects on immunological responses to multivalent vaccines. Applicants have further asserted that the composition being claimed has a property not suggested by the prior art (i.e. induction of anti-HB antibodies).

Applicant's arguments have been carefully considered but not deemed persuasive.

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The claims are drawn to a conjugate composition comprising capsular polysaccharide from *Streptococcus pneumoniae* bacteria linked to immunogenic carrier proteins.

As stated previously, Marburg et al. teach of a conjugate vaccine comprising capsular polysaccharide from *Streptococcus pneumoniae* (Pn) linked to an immunogenic carrier protein. Marburg et al. further teach that composition comprises a mixture of one to ten different pneumococcal polysaccharide-immunogenic protein conjugates thereby meeting the limitation of "n" conjugates. Marburg et al further teach that the polysaccharide may be derived from *Streptococcus pneumoniae* subtypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F thereby meeting the limitation of "derived from *Streptococcus pneumoniae*". The Examiner would also like to point out that Marburg et al teaches that pneumoccal polysaccharide-immunogenic protein conjugates induces a broadly protective immune response. Therefore, the immune response is to the conjugate which comprises a polysaccharide-immunogenic protein (See Abstract). Marburg et al differs from the prior art only in that it does not teach of a conjugate composition comprising capsular polysaccharide from *Streptococcus pneumoniae* linked to an additional protein carrier such as Dt or Tt. However, Matuhashi et al. teaches this limitation. Matuhashi et al. teaches of a process for the production of a composition comprising a covalently attached biologically toxic substance (for example, Dt or Tt) to a saccharide to form a substance-saccharide conjugate.

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Given that 1) Marburg et al. has taught of a conjugate vaccine comprising capsular polysaccharide from *Streptococcus pneumoniae* linked to an immunogenic carrier protein and that 2) Matuhashi et al. has taught of a process for the production of vaccines characterized by covalent attachment of a biologically toxic substance to a saccharide to form a biologically toxic substance-saccharide conjugate it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a conjugate composition comprising capsular polysaccharide from *Streptococcus* linked to more than one immunogenic carrier protein such as Dt or Tt.

The Examiner has noted the applicant remarks on unpredictability of immunological responses to conjugates vaccines taught in the art. However, this is a moot point because the claims do not recite any immunological properties. For example, the claims do not recite that the composition is a conjugate vaccine or that any particular immune response is elicited. Regarding the applicant comments on the composition inducing anti-HB antibodies, this property is not recited in the claims.

6. Claims 1, 8-11, and 16-23 rejected under 35 U.S.C. 103(a) as being anticipated by Marburg and Matuhashi et al. in view of Peeters et al. is **maintained**.

Applicants have asserted that Peeters et al. fails to compensate for the deficiencies of Marburg et al and Matuhashi et al. described above.

Because the Applicants have not presented any specific arguments with regard to the Peeters et al. reference the rejection is being maintained. The Examiners response to the Marburg and Matuhashi et al. references are set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

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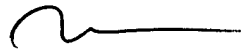
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proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

May 6, 2002



MARK NAVARRO
PRIMARY EXAMINER